K110645
p1/3

JUN - 3 2011

5. 510(k) Summary

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

5.1. Identification:

Manufacturer:	Medis Medizinische Messtechnik GmbH Werner-von-Siemens-Str. 8 D-98693 Ilmenau Germany
Contact Person	Scott Paulson Regulatory Affairs Specialist
Telephone Number:	425.951.6926
Fax Number:	425.491.8356
Repackager/ Relabeler:	SonoSite, Inc. 21919 30th Drive SE Bothell, WA, USA, 98021
Date of Submission:	December 2010

5.2. Device Name:

Trade names:	Bio Z® Cardio Profile
Common Name:	Hemodynamic Monitor
Registration Number:	None
Classification:	II
Classification Name:	Plethysmograph, Impedance Non-invasive blood pressure monitor
Regulation Number:	21 CFR 870.2770 21 CFR 870.1130
Classification Product Code:	DSB, DXN

5.3. Identification of Legally Marketed Predicates:

SonoSite, Inc. believes that the system described within this submission is substantially equivalent to a combination of the CardioDynamics BioZ Rx Hemodynamic Monitor and BioZ Dx Hemodynamic Monitor (K090602, K041294), SphygmoCor CardioVascular Management System (K080670) and the Cheetah Reliant (K103166).

5.4. Device Description:

The Bio Z Cardio Profile Hemodynamic Monitor is a data acquisition system that measures and processes ECG and impedance data. In combination with height, weight, age, and gender the hemodynamic parameters are calculated by the user

software (Cardio Vascular Lab). Additional parameters are measured with the help of OEM modules (NIBP and SpO2) integrated in the device.

The Bio Z Cardio Profile also allows the estimation of the Pulse Wave Velocity (PWV). For this purpose the pressure cuff (NIBP) is placed on the upper leg. The ICG signal is used to define the opening of the aortic valve and the pressure cuff is used to determine the arrival of the pulse wave after leaving the heart. On this basis the propagation time of the pulse wave in the aorta can be estimated. Pulse Wave Velocity can be calculated when considering the distance between the heart and the pressure cuff placed on the upper leg.

The Bio Z Cardio Profile measures SpO_2 for the purpose of calculating Oxygen Delivery Index (DO_2I). The SpO_2 measurements are provided by an integrated OEM module, the Nellcor™ OxiMax™ NELL-1™ OEM pulse oximetry module (previously cleared on the Cheetah Reliant by the FDA (K103166)). The Nell-1 module measures functional oxygen saturation non-invasively via a light signal interacting with tissue, by utilizing the time-varying changes in tissue optical properties that occur with pulsed blood flow. The Nell-1 module receives electrical signals from the sensor, which is then run through an algorithm to provide SpO_2 values.

Utilizing the Nell-1 OEM module, the Bio Z Cardio Profile is capable of measuring:

- Blood oxygen saturation
  (SpO_2 via finger Oximeter) for use in calculating Oxygen Delivery Index (DO_2I); using Oxygen Saturation (SpO_2) data from Oximeter and Cardiac Index (CI) data from the ICG function.

The Nell-1 module, as part of the Bio Z Cardio Profile, is intended for spot-check measurements of arterial blood oxygen saturation. The SpO_2 measurement data is not available to view by the user; it is only used in the calculation of Oxygen Delivery Index (DO_2I), which requires an additional ICG Cardiac Index (CI) measurement.

5.5. Intended Use Statement:

The Bio Z Cardio Profile Hemodynamic Monitor is intended to monitor and display a patient's hemodynamic parameters including:

Heart Rate (HR)
Systolic Blood Pressure (SBP)
Diastolic Blood Pressure (DBP)
Mean Arterial Pressure (MAP)
Pulse Wave Velocity (PWV)
Oxygen Delivery Index (DO_2I)
Stroke Volume (SV)
Stroke Index (SI)
Cardiac Output (CO)
Cardiac Index (CI)
Systemic Vascular Resistance (SVR)
Systemic Vascular Resistance Index (SVRI)
Left Cardiac Work (LCW)
Left Cardiac Work Index (LCWI)
Velocity Index (VI)
Acceleration Index (ACI)
Heather Index (HI)
Pre-Ejection Period (PEP)
Left Ventricular Ejection Time (LVET)
Thoracic Fluid Content (TFC)
Thoracic Fluid Content Index (TFCI)
Baseline Impedance (Z_0)
Total Arterial Compliance (TAC)
Total Arterial Compliance Index (TACI)
Systolic Time Ratio (STR)
Systolic Time Ratio Index (STRI)

The Bio Z Cardio Profile Hemodynamic Monitor is not intended to be used as a vital sign monitor.

5.6. Technological Characteristics:

The Bio Z Cardio Profile transmits current (1.5 mA RMS at 85 kHz) across the thorax. The monitor measures and processes a time-dependent impedance signal, Z(t), which is derived from Ohm's Law as, Z(t) = V(t)/I(t), where I(t) is a time-dependent high frequency current with constant amplitude, injected through the outer electrodes as an auxiliary current into the patient; and V(t) is the resulting time-dependent voltage drop sensed between the inner electrodes. Current amplitude and frequency are within clinically accepted ranges for patient safety.
Both ECG and impedance signals are amplified, filtered, and digitized for further calculation of hemodynamic parameters, as well as for capturing and storing signal waveforms.

Principles of Operation

The Bio Z Cardio Profile Hemodynamic Monitor uses thoracic electrical bioimpedance measurements (also known as TEB or ICG – Impedance Cardiography) to provide information about cardiac function. ICG is a noninvasive technology that determines the mechanical activity of the heart (blood flow) rather than its electrical activity (ECG).

The fundamental theoretical basis of Impedance Cardiography involves direct measurement of base impedance, acceleration index, index of contractility, pre-ejection period, ventricular ejection time and heart rate, and calculations of additional parameters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN - 3 2011

SonoSite, Inc.
c/o Mr. Mark Job
Reviewer
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 53313

Re: K110645
Trade/Device Name: Bio Z Cardio Profile Hemodynamic Monitor
Regulatory Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: II (two)
Product Code: 74 DSB
Dated: May 18, 2011
Received: May 19, 2011

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);.and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110645

4. Indications for Use

510(k) Number (if known):

Device Name: Bio Z® Cardio Profile
Indications for Use:

For the ICG function:
The Bio Z Cardio Profile Hemodynamic Monitor is intended to monitor and display a patient's hemodynamic parameters including;

Heart Rate (HR)
Systolic Blood Pressure (SBP)
Diastolic Blood Pressure (DBP)
Mean Arterial Pressure (MAP)
Pulse Wave Velocity (PWV)
Oxygen Delivery Index (DO_2I)
Stroke Volume (SV)
Stroke Index (SI)
Cardiac Output (CO)
Cardiac Index (CI)
Systemic Vascular Resistance (SVR)
Systemic Vascular Resistance Index (SVRI)
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Total Arterial Compliance Index (TACI)
Systolic Time Ratio (STR)
Systolic Time Ratio Index (STRI)

The Bio Z Cardio Profile Hemodynamic Monitor is not intended to be used as a vital sign monitor.

Prescription Use: X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110645